

INFORMATION DISCLOSURE CITATION

Atty. Docket No.	07680.0018-00000	Appln. No.	10/758,773
Applicant	Seng H. Cheng and David Meeker		
Filing Date	January 16, 2004	Group:	1632

U.S. PATENT DOCUMENTS

Examiner Initial*	Document Number	Issue Date	Name	Class	Sub Class	Filing Date If Appropriate
SM	6,066,626	05/23/00	Yew et al.	514	44	
	5,916,911	06/29/99	Shayman et al.	514	428	
	5,945,442	08/31/99	Shayman et al.	514	428	
	5,952,370	09/14/99	Shayman et al.	514	428	
	6,030,995	02/29/00	Shayman et al.	514	428	
	6,040,332	03/21/00	Shayman et al.	514	428	
	6,051,598	04/18/00	Shayman et al.	514	428	
	5,840,702	11/24/98	Bedwell	514	23	
	6,696,059	06/24/04	Jacob et al.	424	94.61	
	6,495,570	12/17/02	Jacob et al.	514	328	
	20030017139	01/23/03	Souza et al.	424	93.3	05/06/02
	20020142985		Dwek et al.	514	44	10/19/01
	20010044453		Jacob et al.	514	320	05/17/01
SM	20020127213		Jacob et al.	424	94.1	01/22/02

FOREIGN PATENT DOCUMENTS



Document Number	Publication Date	Country	Class	Sub Class	Translation Yes or No
SM WO 00/09153	02/24/00	PCT			
I WO 00/62779	10/26/00	PCT			
SM WO 00/62780	10/26/00	PCT			

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

SM	Abe et al., "Reduction of globotriaosylceramide in Fabry disease mice by substrate deprivation," J. Clin. Invest. 105:563, 2000.
I	Abe et al., "Glycosphingolipid depletion in Fabry disease lymphoblasts with potent inhibitors of glucosylceramide synthase," Kidney International 57:446, 2000.
I	Cox et al., "Novel oral treatment of Gaucher disease with N-leutyldeoxynojirimycin (06T 918) to decrease substrate biosynthesis," Lancet 355:1481, 2000.
SM	Deonarain et al., Exp. Opin. Ther. Patents, 8(1):53,1998.



INFORMATION DISCLOSURE CITATION

Atty. Docket No.	07680.0018-00000	Appln. No.	10/758,773
Applicant	Seng H. Cheng and David Meeker		
Filing Date	January 16, 2004	Group:	1632

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)	
	Desnick et al., "Fabry disease, an under-recognized multisystemic disorder: expert recommendations for diagnosis, management, and enzyme replacement therapy," Annals Int. Med. 138:338, 2003.
	Eck et al., Goodman and Gilman's The Pharmacological Basis of Therapeutics, Ninth Edition, McGraw-Hill, New York, 1996, p 77-101.
	Eng et al., "Safety and efficacy of recombinant human alpha-galactosidase A--replacement therapy in Fabry's disease," N. Engl. J. Med. 345:9, 2001.
	Gorecki, Expert Opin. Emerging Drugs, 6(2):187.
	Ioannou et al., "Fabry disease: preclinical studies demonstrate the effectiveness of alpha-galactosidase A replacement in enzyme-deficient mice," Am. J. Hum. Genet. 68:14, 2001.
	Jeyakumar et al., "Delayed symptom onset and increased life expectancy in Sandhoff disease mice treated with N-butyldeoxynojirimycin," Proc. Natl. Acad. Sci. USA 96:6388, 1999.
	Jung et al., "Adeno-associated viral vector-mediated gene transfer results in long-term enzymatic and functional correction in multiple organs of Fabry mice," Proc. Natl. Acad. Sci. USA 98:2676.
	Kakkis et al., "Overexpression of the human lysosomal enzyme alpha-L-iduronidase in Chinese hamster ovary cells," Prot. Express. Purif. 5:225, 1994.
	Kakkis et al., "Long-term and high-dose trials of enzyme replacement therapy in the canine model of mucopolysaccharidosis I," Biochem. Molec. Med. 58:156, 1996.
	Keeling et al., "Gentamicin-mediated suppression of Hurler syndrome stop mutations restores a low level of alpha-L-iduronidase activity and reduces lysosomal glycosaminoglycan accumulation," Hum. Molec. Genet. 10:291, 2001.
	Kikuchi et al., "Clinical and metabolic correction of pompe disease by enzyme therapy in acid maltase-deficient quail," J. Clin. Invest. 101:827, 1998.
	Lee et al., "Improved inhibitors of glucosylceramide synthase," J. Biol. Chem. 274:14662, 1999.
	Medin et al., "Correction in trans for Fabry disease: expression, secretion and uptake of alpha-galactosidase A in patient-derived cells driven by a high-titer recombinant retroviral vector," Proc. Natl. Acad. Sci. USA 93:7917, 1996.
	Neufeld et al., "Lysosomal storage diseases," Annu. Rev. Biochem. 60:257, 1991.
	Oshima et al., "Cloning, sequencing, and expressin of cDNA for human beta-glucuronidase," Proc. Natl. Acad. Sci. USA 81:685, 1987.
	Overkleeft et al., "Generation of specific deoxynojirimycin-type inhibitors of the non-lysosomal glucosylceramidase," J. Biol. Chem. 273(41):26522, 1998.
	Park et al., "Long-term correction of globotriaosylceramide storage in Fabry mice by recombinant adeno-associated virus-mediated gene transfer," Proc. Natl. Acad. Sci. USA 100:3450, 2003.
	Pauly et al., "Complete correction of acid alpha-glucosidase deficiency in Pompe disease fibroblasts in vitro, and lysosomally targeted expression in neonatal rat cardiac and skeletal muscle," Gene Therapy 5:473, 1998.

INFORMATION DISCLOSURE CITATION

Atty. Docket No.	07680.0018-00000	Appln. No.	10/758,773
Applicant	Seng H. Cheng and David Meeker		
Filing Date	January 16, 2004	Group:	1632

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)	
	Platt et al., "Prevention of lysosomal storage in Tay-Sachs mice treated with N-butyldeoxynojirimycin," Science 276:428, 1997.
	Ponce et al., "Enzyme therapy in Gaucher disease type 1: effect of neutralizing antibodies to acid beta-glucosidase," Blood 90:43, 1997.
	Schiffmann et al., "Enzyme replacement therapy in Fabry disease: a randomized controlled trial," JAMA 285:2743, 2001.
	Schiffmann et al., "Infusion of alpha-galactosidase A reduces tissue globotriasylceramide storage in patients with Fabry disease," Proc. Natl. Acad. Sci. USA, 97(1):365, 2000.
	Shayman et al., "Inhibitors of glucosylceramide synthase," Meth. Enzymol. 311:373, 2000.
	Shull et al., "Enzyme replacement in a canine model of Hurler syndrome," Proc. Natl. Acad. Sci. USA 91:12937, 1998.
	Takahashi et al., "E1B-55K-deleted adenovirus expressing E1A-13S by AFP-enhancer/promoter is capable of highly specific replication in AFP-producing hepatocellular carcinoma and eradication of established tumor," Mol. Ther. 5:627, 2002.
	Van Der Ploeg et al., "Breakdown of lysosomal glycogen in cultured fibroblasts from glycogenosis type II patients after uptake of acid alpha-glucosidase," J. Neurolog. Sci. 79:327, 1987.
	Van Der Ploeg, et al., "Intravenous administration of phosphorylated acid alpha-glucosidase leads to uptake of enzyme in heart and skeletal muscle of mice," J. Clin. Invest. 87:513, 1991.
	Van Der Ploeg et al., "Prospect for enzyme therapy in glycogenosis II variants: a study on cultured muscle cells," J. Neurol. 235:392, 1998.
	Van Der Ploeg et al., "Receptor-mediated uptake of acid alpha-glucosidase corrects lysosomal glycogen storage in cultured skeletal muscle," Pediatr. Res. 24:90, 1988.
	Van Hove et al., "High-level production of recombinant human lysosomal acid alpha-glucosidase in Chinese hamster ovary cells which targets to heart muscle and corrects glycogen accumulation in fibroblasts from patients with Pompe disease," Proc. Natl. Acad. Sci. USA 93:65, 1996.
	Zaretsky et al., "Retroviral transfer of acid alpha-glucosidase cDNA to enzyme-deficient myoblasts results in phenotypic spread of the genotypic correction by both secretion and fusion," Human Gene Therapy 8:1555, 1997.
	Ziegler et al., "Correction of the nonlinear dose response improves the viability of adenoviral vectors for gene therapy of Fabry disease," Human Gene Ther. 13:935, 2002.
	Ziegler et al., "Correction of enzymatic and lysosomal storage defects in Fabry mice by adenovirus-mediated gene transfer," Human Gene Ther. 10:1667, 1999.

INFORMATION DISCLOSURE CITATION

Atty. Docket No.	07680.0018-00000	Appln. No.	10/758,773
Applicant	Seng H. Cheng and David Meeker		
Filing Date	January 16, 2004	Group:	1632
Examiner	<i>SV Chen</i>		
Date Considered	<i>5-21-07</i>		
*Examiner:	Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.		
Form PTO 1449	Patent and Trademark Office - U.S. Department of Commerce		

IDS Form PTO/SB/08: Substitute for form 1449A/PTO

Complete if Known

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet 1 of 7

Application Number 10/758,773

Filing Date January 16, 2004

First Named Inventor Seng H. CHENG

Art Unit 1632

Examiner Name Shin-Lin CHEN

Attorney Docket Number 07680.0018-00000

U.S. PATENTS AND PUBLISHED U.S. PATENT APPLICATIONS					
Examiner Initials	Cite No. ¹	Document Number	Issue or Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
42	1	US-5,049,386	09/17/1991	Eppstein et al.	
	2	US-5,236,838	08/17/1993	Rasmussen et al.	
	3	US-5,264,618	11/23/1993	Felgner et al.	
	4	US-5,272,071	12/21/1993	Chappel	
	5	US-5,279,833	01/18/1994	Rose	
	6	US-5,283,185	02/01/1994	Epand et al.	
	7	US-5,334,761	08/02/1994	Gebeyehu et al.	
	8	US-5,549,892	08/27/1996	Friedman et al.	
	9	US-5,580,859	12/03/1996	Felgner et al.	
	10	US-5,650,096	07/22/1997	Harris et al.	
	11	US-5,670,488	09/23/1997	Gregory et al.	
	12	US-5,707,618	01/13/1998	Armentano et la.	
	13	US-5,719,131	02/17/1998	Harris et al.	
	14	US-5,747,471	05/05/1998	Siegel et al.	
	15	US-5,753,500	05/19/1998	Shenk et al.	
	16	US-5,757,471	05/26/1998	Itoh et al.	
	17	US-5,767,099	06/16/1998	Harris et al.	
	18	US-5,783,565	07/21/1998	Lee et al.	
	19	US-5,824,544	10/20/1998	Armentano et al.	
	20	US-5,830,462	11/03/1998	Crabtree et al.	
	21	US-5,840,710	11/24/1998	Lee et al.	
	22	US-5,856,152	01/05/1999	Wilson et al.	
	23	US-5,861,397	01/19/1999	Wheeler	
	24	US-5,866,755	02/02/1999	Bujard et al.	
	25	US-5,869,337	02/09/1999	Crabtree et al.	
	26	US-5,871,753	02/16/1999	Crabtree et al.	
	27	US-5,874,534	02/23/1999	Vegeto et al.	
	28	US-5,882,877	03/16/1999	Gregory et al.	
	29	US-5,910,487	06/08/1999	Yew et al.	
	30	US-5,910,488	06/08/1999	Nabel et al.	
	31	US-5,912,239	06/15/1999	Siegel et al.	
	32	US-5,925,628	07/20/1999	Lee et al.	
	33	US-5,935,934	08/10/1999	Vegeto et al.	
42	34	US-5,935,936	08/10/1999	Fasbender et al.	

IDS Form PTO/SB/08: Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Complete if Known	
				Application Number	10/758,773
				Filing Date	January 16, 2004
				First Named Inventor	Seng H. CHENG
				Art Unit	1632
				Examiner Name	Shin-Lin CHEN
Sheet	2	of	7	Attorney Docket Number	07680.0018-00000

U.S. PATENTS AND PUBLISHED U.S. PATENT APPLICATIONS					
35	US-5,939,401	08/17/1999	Marshall et al.		
36	US-5,942,634	08/24/1999	Siegel et al.		
37	US-5,948,767	09/07/1999	Scheule et al.		
38	US-5,948,925	09/07/1999	Keynes et al.		
39	US-5,952,916	09/14/1999	Yamabe		
40	US-5,962,313	10/05/1999	Podsakoff et al.		
41	US-5,963,622	10/05/1999	Walsh		
42	US-5,968,502	10/19/1999	Treco et al.		
43	US-5,994,127	11/30/1999	Selden et al.		
44	US-5,994,136	11/30/1999	Naldini et al.		
45	US-5,994,313	11/30/1999	Crabtree et al.		
46	US-5,994,317	11/30/1999	Wheeler		
47	US-6,004,941	12/21/1999	Bujard et al.		
48	US-6,011,018	01/04/2000	Crabtree et al.		
49	US-6,013,516	01/11/2000	Verma et al.		
50	US-6,022,874	02/08/2000	Wheeler		
51	US-6,040,174	03/21/2000	Imler et al.		
52	US-6,048,524	04/11/2000	Selden et al.		
53	US-6,048,724	04/11/2000	Selden et al.		
54	US-6,048,729	04/11/2000	Selden et al.		
55	US-6,054,288	04/25/2000	Selden et al.		
56	US-6,063,630	05/16/2000	Treco et al.		
57	US 2005/0075305	04/07/2005	Dwek et al.		

Note: Submission of copies of U.S. Patents and published U.S. Patent Applications is not required.

FOREIGN PATENT DOCUMENTS						
Examiner Initials	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	Translation ⁸
		Country Code ³ Number ⁴ Kind Code ⁵ (if known)				
58	EP 1 171 128		06/18/2003	Dwek et al.		
59	WO 95/06743		03/09/2005	Dong et al.		
60	WO 95/29993		11/09/1995	Nabel et al.		
61	WO 95/33052		12/07/2005	Berlin et al.		
62	WO 96/33280		10/24/1996	Zhang et al.		
63	WO 96/40955		12/19/1996	Graham et al.		
64	WO 96/41865		12/27/1996	Clackson et al.		
65	WO 97/00326		01/03/1997	Falloux et al.		

IDS Form PTO/SB/08: Substitute for form 1449A/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Application Number	10/758,773
				Filing Date	January 16, 2004
				First Named Inventor	Seng H. CHENG
				Art Unit	1632
				Examiner Name	Shin-Lin CHEN
Sheet	3	of	7	Attorney Docket Number	07680.0018-00000

FOREIGN PATENT DOCUMENTS					
66	WO 97/09441	03/13/1997	Wadsworth et al.		
67	WO 97/25446	07/17/1997	Kaleko et al.		
68	WO 98/11206	03/19/1998	Selden et al.		
69	WO 99/41399	08/19/1999	Wadsworth		
70	WO 99/57296	11/11/1999	Wadsworth et al.		
71	PCT/US99/03483	08/19/1999	Wadsworth et al.		

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	Translation ²
66	72	Andersson et al., 2000, <i>Biochem. Pharmacol.</i> 59, 821-829 (N-butyldeoxygalactonojirimycin as a more selective inhibitor than NB-DNJ).	
67	73	Barbon et al., <i>Mol. Ther.</i> 12:431-440 (2004). AAV8-Mediated Hepatic Expression of Acid Sphingomyelinase Corrects the Metabolic Defect in the Visceral Organs of a Mouse Model of Niemann-Pick Disease.	
68	74	Barton et al., 1991, Replacement Therapy for Inherited Enzyme Deficiency – Macrophage-targeted Glucocerebrosidase for Gaucher's Disease, <i>New England Journal of Medicine</i> 324, 1464-1470.	
69	75	Behr et al., <i>Proc. Natl. Acad. Sci. USA</i> , 86, 6982-6986 (1989).	
70	76	Benjaminovitz et al., 2000, <i>N. Engl. J. Med.</i> 342, 613-619.	
71	77	Berard et al., 1999, <i>Pharmacotherapy</i> 19, 1127-1137.	
72	78	Berkner, K.L., 1992, <i>Curr. Top. Micro. Immunol.</i> 158, 39-66.	
73	79	Beutler et al., 1996, <i>Proc. Assoc. Am. Phys.</i> 108, 179-84.	
74	80	Bodamer, O.A.F. et al., 1997, Dietary Treatment in Late-Onset Acid Maltase Deficiency, <i>Eur. J. Pediatr.</i> 156, S39-S42.	
75	81	Bosselman et al., 1987, <i>Molec. Cell. Biol.</i> 7(5):1797-1806.	
76	82	Brady, R.O. et al., Enzyme Replacement Therapy in Fabry Disease, <i>J. Inher. Metab. Dis.</i> , 24:18-24, 2001.	
77	83	Branco et al., 1999, <i>Transplantation</i> 68, 1588-1596.	
78	84	Brooks, D.A., Immune Response to Enzyme Replacement Therapy in Lysosomal Storage Disorder Patients and Animal Models, <i>Mol. Genet. and Metab.</i> , 68:268-275, 1999.	
79	85	Burch, Mark M. et al., Adenovirus-mediated regulable target gene expression <i>in vivo</i> , <i>Proc. Natl. Acad. Sci. USA</i> , 96:355-360, 1999.	
80	86	Chang, Benny H-J. et al., Liver-specific Inactivation of the Abetalipoproteinemia Gene Completely Abrogates Very Low density Lipoprotein/Low Density Lipoprotein Production in a Viable Conditional Knockout Mouse, <i>Jour. Bio. Chem.</i> , 274:6051-6055, 1999.	
81	87	Chao, H. et al., Sustained expression of human factor VIII in mice using a parvovirus-based vector, <i>Blood</i> , 95:1594-1599, 2000.	
82	88	Chejanovsky and Carter, 1989, <i>Virology</i> 171:239.	
83	89	Chirmule et al., 2000, <i>J. Virol.</i> 74, 3345-3352.	
84	90	Chung et al. 1997, <i>Proc. Natl. Acad. Sci. USA</i> 94: 575.	
85	91	Clark et al., <i>Gene Therapy</i> 3:1124-1132, 1996.	
86	92	Clark et al., <i>Human Gene Therapy</i> 6:1329-1341, 1995.	
87	93	Cleary, M.A. and Wraith, J.E., 1995, The Presenting Features of Mucopolysaccharidosis Type IH (Hurler Syndrome), <i>Acta. Paediatr.</i> 84, 337-339.	
88	94	Colville, G.A. and Bax, M.A., 1996, Early Presentation in the Mucopolysaccharide Disorders, <i>Child: Care, Health and Development</i> 22, 31-36.	

IDS Form PTO/SB/08: Substitute for form 1449A/PTO			Complete if Known		
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)			Application Number	10/758,773	
			Filing Date	January 16, 2004	
			First Named Inventor	Seng H. CHENG	
			Art Unit	1632	
			Examiner Name	Shin-Lin CHEN	
			Attorney Docket Number	07680.0018-00000	
Sheet	4	of	7		

NON PATENT LITERATURE DOCUMENTS				
95	Connelly, S. et al., Sustained Expression of Therapeutic Levels of Human Factor VIII in Mice, <i>Blood</i> , 87:4671-4677, 1996.			
96	Connelly, S. et al., Sustained Phenotypic Correction of Murine Hemophilia A by In Vivo Gene Therapy, <i>Blood</i> , 81:3273-3281, 1998.			
97	Cristiano et al., Hepatic gene therapy:Efficient gene delivery and expression in primary hepatocytes utilizing a conjugated adenovirus-DNA complex, <i>Proc. Natl. Acad. Sci. USA</i> 90, 11548-11552, 1993.			
98	Curiel et al., 1991, <i>Proc. Natl. Acad. Sci. USA</i> 88, 8850.			
99	Czartoryska et al., 2000, <i>Clin. Biochem.</i> 33, 147 149.			
100	Czartoryska et al., 1998, <i>Clin. Biochem.</i> 31, 417 420.			
101	Danos and Mulligan, 1988, <i>Proc. Natl. Acad. Sci.</i> 85:6460-6464.			
102	Den Tandt et al., 1996, <i>J. Inherit. Metab. Dis.</i> 19, 344 350.			
103	Desnick et al., <i>Proc. Natl. Acad. Sci. U.S.A.</i> 76:5326-5330 (1979).			
104	Desnick, R.J. et al., 1995, α -Galactosidase A Deficiency: Fabry Disease, in: The Metabolic and Molecular Bases of Inherited Disease, Scriver et al., eds., McGraw-Hill, New York, 7th ed., pages 2741-2784.			
105	Dodelson de Kremer et al., 1997, <i>Medicina</i> (Buenos Aires) 57, 677 684.			
106	Drucker et al., 1993, <i>Hum. Mutat.</i> 2, 415-7.			
107	Duzgunes et al., 1993, <i>Meth. Enzymol.</i> 5, 303-307.			
108	Eckhoff et al., 2000, <i>Transplantation</i> 69, 1867 1872.			
109	Ekberg et al., 2000, <i>Transpl. Int.</i> 13, 151 159.			
110	Embretson and Temin, 1987, <i>J. Virol.</i> 61(9):2675-2683.			
111	Ensinger et al., <i>J. Virol.</i> 10:328-339, 1972.			
112	Fairbairn et al., 1996, Long-Term In vitro Correction of α -L-Iduronidase Deficiency (Hurler Syndrome) in Human Bone Marrow, <i>Proc. Natl. Acad. Sci. U.S.A.</i> 93, 2025-2030.			
113	Felgner et al., 1994, <i>J. Biol. Chem.</i> 269, 2550-2561.			
114	Felgner, et al., <i>Proc. Natl. Acad. Sci. USA</i> , 84, 7413-7417 (1987).			
115	Felice, K.J. et al., 1995, Clinical Variability in Adult-Onset Acid Maltase Deficiency: Report of Affected Sibs and Review of the Literature, <i>Medicine</i> 74, 131-135.			
116	Fisher et al., <i>Virology</i> 217:11-22, 1996.			
117	Fishwild et al., 1999, <i>Clin. Immunol.</i> 92, 138 152.			
118	Flotte, F.R. et al., <i>Gene Therapy</i> 2:29-37, 1995.			
119	Gaziev et al., 1999, Bone Marrow Transplant. 25, 689 696.			
120	Gottschalk et al., 1994, <i>Gene Ther.</i> 1, 185.			
121	Grabowski et al., 1995, Enzyme Therapy in Type 1 Gaucher Disease: Comparative Efficacy of Mannose-terminated Glucocerebrosidase from Natural and Recombinant Sources, <i>Annals of Internal Medicine</i> 122, 33-39.			
122	Grady, D., <i>The New York Times</i> , Saturday, May 27, 2000, pages A1 and A11.			
123	Grewal R.P., 1994, Stroke in Fabry's Disease, <i>J. Neurol.</i> 241, 153-156.			
124	Grimm et al., <i>Hum. Gene Ther.</i> 9:2745-2760, 1998.			
125	Guffon N. et al., 1998, Follow-up of Nine Patients with Hurler Syndrome After Bone Marrow Transplantation, <i>J. Pediatr.</i> 133, 119-125.			
126	Gullingsrud E.O. et al., 1998, Ocular Abnormalities in the Mucopolysaccharidoses After Bone Marrow Transplantation, <i>Ophthalmology</i> 105, 1099-1105.			
127	Gummert et al., 1999, <i>J. Am. Soc. Nephrol.</i> 10, 1366 1380.			

IDS Form PTO/SB/08: Substitute for form 1449A/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Application Number	10/758,773
				Filing Date	January 16, 2004
				First Named Inventor	Seng H. CHENG
				Art Unit	1632
				Examiner Name	Shin-Lin CHEN
Sheet	5	of	7	Attorney Docket Number	07680.0018-00000

NON PATENT LITERATURE DOCUMENTS					
128	Guo et al., 1995, <i>J. Inherit. Metab. Dis.</i> 18, 717 722.				
129	Hara et al., 1994, <i>Hum. Genet.</i> 94, 136-40.				
130	Hardy et al., <i>J. Virol.</i> 71:1842-1849, 1997.				
131	Harris, Julian D. et al., Acute regression of advanced and retardation of early aortic atheroma in immunocompetent apolipoprotein-E (apoE) deficient mice by administration of a second generation [E1-, E3-, polymerase-] adenovirus vector expressing human apoE, <i>Hum. Mol. Genet.</i> , 11:43-58, 2002.				
132	Henry, 1999, <i>Clin. Transplant.</i> 13, 209 220.				
133	Hers, H.G., "Inborn Lysosomal Diseases", <i>Gastroenterology</i> , vol. 48(5), 625-633, 1965.				
134	Hirschhorn R., 1995, Glycogen Storage Disease Type II: Acid α -Glucosidase (Acid Maltase) Deficiency, In: <i>The Metabolic and Molecular Bases of Inherited Disease</i> , Scriver et al., eds., McGraw-Hill, New York, 7th ed., pages 2443-2464.				
135	Hollak et al., 1994, <i>J. Clin. Invest.</i> 93, 1288 1292.				
136	Hong et al., 2000, <i>Semin. Nephrol.</i> 20, 108 125.				
137	Horwitz, M.S., <i>Adenoviruses</i> , Virology, 3rd edition, Fields et al., eds., Raven Press, New York, 1996.				
138	Ideguchi et al., 2000, <i>Neuroscience</i> 95, 217 226.				
139	Ioannou et al., <i>Am. J. Hum. Genet.</i> , 59:A15, 1996.				
140	Ito et al., 2000, <i>J. Immunol.</i> 164, 1230 1235.				
141	Jeyakumar et al., 2001, <i>Blood</i> 97, 327-329 (NB-DNJ therapy plus bone marrow transplantation).				
142	Jolly, D., <i>Cancer Gene Therapy</i> 1:51-64, 1994.				
143	Kakkis et al., <i>PNAS</i> , 101:829-834, 2004.				
144	Kaleko, M. et al., Exploring gene therapy vectors, <i>Hemaware</i> , 28-33, 2001.				
145	Kelly, et al., "Primary structure of bovine adenosine deaminase," <i>J. Pharm. and Biomed. Analysis</i> , 14, 1513-1519, 1996.				
146	Ko, Y.H. et al., 1996, Atypical Fabry's Disease - An Oligosymptomatic Variant, <i>Arch. Pathol. Lab. Med.</i> 120, 86-89.				
147	Kochanek et al., <i>Proc. Natl. Acad. Sci. USA</i> 93:5731-5736, 1996.				
148	Kolodny et al., 1998, "Storage Diseases of the Reticuloendothelial System", In: <i>Nathan and Oski's Hematology of Infancy and Childhood</i> , 5th ed., vol. 2, David G. Nathan and Stuart H. Orkin, Eds., W.B. Saunders Co., pages 1461-1507.				
149	Kotlin et al., <i>Proc. Natl. Acad. Sci.</i> 87:2211-2215, 1990.				
150	Kupfer et al., 1994, <i>Hum. Gene Ther.</i> 5, 1437.				
151	Kurlberg et al., 2000, <i>Scand. J. Immunol.</i> 51, 224 230.				
152	Laughlin et al. 1983, <i>Gene</i> 23:65.				
153	Leonard et al., 2000, <i>J. Allergy Clin. Immunol.</i> 105, 877-888.				
154	Lieber et al., <i>J. Virol.</i> 70:8944-8960, 1996.				
155	Mann et al., 1983, <i>Cell</i> 33:153-159.				
156	Marinova Mutafchieva et al., 2000, <i>Arthritis Rheum.</i> 43, 638 644.				
157	Markowitz et al., 1988, <i>J. Virol.</i> 62(4):1120-1124.				
158	Masterson E.L. et al., 1996, Hip Dysplasia in Hurler's Syndrome: Orthopaedic Management After Bone Marrow Transplantation, <i>J. Pediatric Orthopaedics</i> 16, 731-733.				
159	Mendez M.F. et al., 1997, The Vascular Dementia of Fabry's Disease, <i>Dement. Geriatr. Cogn. Disord.</i> 8, 252-257.				

IDS Form PTO/SB/08: Substitute for form 1449A/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Application Number	10/758,773
				Filing Date	January 16, 2004
				First Named Inventor	Seng H. CHENG
				Art Unit	1632
				Examiner Name	Shin-Lin CHEN
Sheet	6	of	7	Attorney Docket Number	07680.0018-00000

NON PATENT LITERATURE DOCUMENTS			
160	Miller, 1992, <i>Nature</i> 357, 455-460.		
161	Mistry et al., 1997, <i>Baillieres Clin. Haematol.</i> 10, 817 838.		
162	Moder, 2000, <i>Ann. Allergy Asthma Immunol.</i> 84, 280 284.		
163	Morales, 1996, Gaucher's Disease: A Review, <i>The Annals of Pharmacotherapy</i> 30, 381-388.		
164	Morral et al., <i>Hum. Gene Ther.</i> 10:2709-2716, 1998.		
165	Muzyczka, N., <i>Curr. Top. Micro. Immunol.</i> 158: 97-129, 1992.		
166	Nakao S., 1995, An Atypical Variant of Fabry's Disease in Men with Left Ventricular Hypertrophy, <i>N. Engl. J. Med.</i> 333, 288-293.		
167	Neufeld et al., 1995, The Mucopolysaccharidoses, In: <i>The Metabolic and Molecular Bases of Inherited Diseases</i> , Scriver et al., eds., McGraw-Hill, New York, 7th ed., pages 2465-2494.		
168	Nevins, 2000, <i>Curr. Opin. Pediatr.</i> 12, 146 150.		
169	Oberholzer et al., 2000, <i>Crit. Care Med.</i> 28 (4 Suppl.), N3-N12.		
170	Ohshima, α -Galactosidase A deficient mice: A model of Fabry disease, <i>Proc. Natl. Acad. Sci. USA</i> , 97:2540-2544, 1997.		
171	Okumiya et al., 1996, <i>Jpn. J. Hum. Genet.</i> 41, 313-21.		
172	Parks et al., <i>Proc. Natl. Acad. Sci. USA</i> 93:13565-13570, 1996.		
173	Pastore et al. 1999, <i>Hum. Gene Ther.</i> 10:1773.		
174	Pastores et al., 1993, <i>Blood</i> , 82:408-416.		
175	Peltola et al., 1994, <i>Hum. Molec. Genet.</i> 3, 2237-2242.		
176	Peters C. et al., 1998, Hurler Syndrome: II. Outcome of HLA-Genotypically Identical Sibling and HLA-Haploidentical: Related Donor Bone Marrow Transplantation in Fifty-Four Children, <i>Blood</i> 91, 2601-2608.		
177	Peters C. et al., 1998, Hurler Syndrome: Past, Present and Future, <i>J. Pediatr.</i> 133, 7-9.		
178	Ponnazhagan et al., <i>Hum. Gene Ther.</i> 8:275-284, 1997.		
179	Ponticelli et al., 1999, <i>Drugs R. D.</i> 1, 55 60.		
180	Potter et al., 1999, <i>Ann. N.Y. Acad. Sci.</i> 875, 159 174.		
181	Przepiorka et al., 1998, <i>Blood</i> 92, 4066 4071.		
182	Qi et al., 2000, <i>Transplantation</i> 69, 1275 1283.		
183	Reuser A.J. et al., 1995, Glycogenosis Type II (Acid Maltase Deficiency), <i>Muscle & Nerve Supplement</i> 3, S61-S69.		
184	Rosenthal et al., 1995, Enzyme Replacement Therapy for Gaucher Disease: Skeletal Responses to Macrophage-targeted Glucocerebrosidase, <i>Pediatrics</i> 96, 629-637.		
185	Rubinstein et al., 1998, <i>Cytokine Growth Factor Rev.</i> 9, 175-181.		
186	Ryan et al., 2001, <i>Diabetes</i> 50, 710 719.		
187	Sakuraba et al., 1990, <i>Am. J. Hum. Genet.</i> 47, 784-9.		
188	Salvetti et al., <i>Hum. Gene Ther.</i> 9:695-706, 1998.		
189	Sands, Mark S. et al., Murine Mucopolysaccharidosis Type VII: Long Term Therapeutic Effects of Enzyme Replacement and Enzyme Replacement Followed by Bone Marrow Transplantation, <i>J. Clin. Invest.</i> , 99:1596-1605, 1997.		
190	Shapiro, A.M. et al., July 27, 2000, "Islet Transplantation in Seven Patients With Type 1 Diabetes Mellitus Using A Glucocorticoid Free Immunosuppressive Regimen", <i>N. Engl. J. Med.</i> 343, 230 238.		
191	Shelley E.D. et al., 1995, Painful Fingers, Heat Intolerance, and Telangiectases of the Ear: Easily Ignored Childhood Signs of Fabry Disease, <i>Pediatric Derm.</i> 12, 215-219.		
192	Slatskas, C. et al., Gene therapy for Fabry disease, <i>J. Inherit. Metab. Dis.</i> , 24:25-41, 2001.		

IDS Form PTO/SB/08: Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)			Complete if Known		
			Application Number	10/758,773	
			Filing Date	January 16, 2004	
			First Named Inventor	Seng H. CHENG	
			Art Unit	1632	
			Examiner Name	Shin-Lin CHEN	
Sheet	7	of	7	Attorney Docket Number	07680.0018-00000

NON PATENT LITERATURE DOCUMENTS			
42	193	Slavik et al., 1999, <i>Immunol. Res.</i> 19, 1 24.	
	194	Takahashi et al., 1992, <i>J. Biol. Chem.</i> 267, 12552-8.	
	195	Tanaka et al., 1999, <i>J. Hum. Genet.</i> 44, 91-5.	
	196	Van Heest A.E. et al., 1998, Surgical Treatment of Carpal Tunnel Syndrome and Trigger Digits in Children with Mucopolysaccharide Storage Disorders, <i>J. Hand Surgery</i> 23A, 236-243.	
	197	Verma et al., <i>Nature</i> 389:239-242 (1997).	
	198	Vincent et al., <i>J. Virol.</i> 71:1897-1905, 1997.	
	199	Voskoboeva et al., 1994, <i>Hum. Genet.</i> 93, 259-64.	
	200	Wagner et al., 1992, <i>Proc. Natl. Acad. Sci. USA</i> 89, 6099.	
	201	Wang et al. 2000, <i>Mol. ther.</i> 1:154.	
	202	Watanabe and Temin, 1983, <i>Molec. Cell. Biol.</i> 3(12):2241-2249.	
	203	Wilcox, William R. et al., Long-Term safety and Efficacy of Enzyme Replacement Therapy for Fabry Disease, <i>Am. J. Hum. Genet.</i> , 75:65-74, 2004.	
	204	Wiseman et al., 1999, <i>Drugs</i> 58, 1029 1042.	
	205	Wivel et al., Adenovirus Vectors, The Development of Human Gene Therapy, Friedman, T. ed., Cold Spring Harbor Laboratory Press, New York, 87-110, 1999.	
	206	Wu et al., Incorporation of Adenovirus into a Ligand-based DNA Carrier System Results in Retention of Original Receptor Specificity and Enhances Targeted Gene Expression, <i>J. Biol. Chem.</i> , 269:11542-11546, 1994.	
	207	Yang et al., 1993, <i>Biochim. Biophys. Acta</i> 1182, 245-9.	
	208	Yang, Q. et al., <i>J. Virol.</i> 68: 4847-4856, 1994.	
	209	Yew, N. et al. 2002, <i>Mol. Ther.</i> , 5:731-738.	
	210	Yoshimura et al., 1993, <i>J. Biol. Chem.</i> 268, 2300.	
	211	Young et al., 1997, <i>J. Inherlt. Metab. Dis.</i> 20, 595 602.	
	212	Zhang et al., 1994, <i>Hum. Molec. Genet.</i> 3, 139-145.	
42	213	Ziegler et al., <i>Mol. Ther.</i> 8:231-240 (2004). AAV2 Vector Harboring a Liver-Restricted Promoter Facilitates Sustained Expression of Therapeutic Levels of α -Galactosidase A and the Induction of Immune Tolerance in Fabry Mice.	

Examiner Signature	<i>S. Chen</i>	Date Considered	5-21-07
--------------------	----------------	-----------------	---------

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.